

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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TAKEDA CHEMICAL INDUSTRIES, LTD. and
TAKEDA PHARMACEUTICALS NORTH AMERICA,
INC.,

Plaintiffs,

-v-

MYLAN LABORATORIES, INC., MYLAN
PHARMACEUTICALS, INC., and UDL
LABORATORIES, INC.,

Defendants.

TAKEDA CHEMICAL INDUSTRIES, LTD. and
TAKEDA PHARMACEUTICALS NORTH AMERICA,
INC.,

Plaintiffs,

-v-

RANBAXY LABORATORIES, LTD., and RANBAXY
PHARMACEUTICALS, INC.,

Defendants.

TAKEDA CHEMICAL INDUSTRIES, LTD. and
TAKEDA PHARMACEUTICALS NORTH AMERICA,
INC.,

Plaintiffs,

-v-

WATSON PHARMACEUTICALS, INC., WATSON
LABORATORIES, INC., WATSON PHARMA,
INC., and DANBURY PHARMACAL, INC.,

Defendants.

TAKEDA CHEMICAL INDUSTRIES, LTD. and
TAKEDA PHARMACEUTICALS NORTH AMERICA,
INC.,

Plaintiffs,

-v-

ALPHAPHARM PTY. LTD. and GENPHARM,

03 CIV. 8253 (DLC)

OPINION & ORDER

03 CIV. 8250

03 CIV. 8254

04 CIV. 1966

INC.,

Defendants.

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Appearances:

For Plaintiffs:

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For Defendants Alphapharm Pty. Ltd. and
Genpharm, Inc.:

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DENISE COTE, District Judge:

Alphapharm Pty. Ltd. and Genpharm, Inc. ("Alphapharm") have moved in limine to exclude portions of the direct testimony from experts for Takeda Chemical Industries, Ltd. and Takeda Pharmaceuticals North America, Inc. ("Takeda"). The direct testimony for this bench trial was submitted in advance of trial through affidavits. This Opinion and Order addresses the motions as to Takeda experts William Kettyle ("Kettyle") and Silvio Inzucchi ("Inzucchi"). For the following reasons, Alphapharm's motions are denied.

In 2004, Alphapharm sent Takeda notice that it had filed an Abbreviated New Drug application to market a generic version of Takeda's drug pioglitazone, marketed under the commercial name ACTOS®, and that Alphapharm had certified in its application that the patents protecting pioglitazone were invalid or

unenforceable. Alphapharm specifically claims that the '777 Patent, which protects the chemical compound for pioglitazone, is invalid due to obviousness. On March 12, 2004, Takeda brought suit against Alphapharm for infringement of the '777 Patent.

Alphapharm moves to preclude Kettyle's testimony because he is not qualified to offer certain opinions, and because his opinions are not supported by sufficient data and are speculative. Alphapharm particularly objects to Kettyle's opinions regarding the prescribing practices of physicians, which Kettyle admits are based on his own experience and conversations with his colleagues.

Alphapharm has moved to preclude testimony from Inzucchi because his opinions about the prescribing practices of other physicians are based on his own experiences, rather than on data, and as a result are unreliable and speculative. Alphapharm also points to Inzucchi's criticism, at his deposition in September 2005, of scientific literature on which he based several of his opinions about the effects and success of pioglitazone. Alphapharm points to Inzucchi's statements as evidence that the opinions based on that literature should be excluded as unreliable and speculative.

Both Kettyle and Inzucchi are endocrinologists with impressive academic credentials and extensive practical experience. Their backgrounds clearly qualify them to offer opinions as to why physicians prescribe medications in general and the pharmaceutical choices made in treating diabetes in particular. Alphapharm's contentions as to the probative value of their testimony are properly addressed through cross-


examination at trial.

Conclusion

Having considered Alphapharm's arguments in support of its motions to preclude the testimony of Inzucchi and Kettyle, Alphapharm's motions are denied.

SO ORDERED:

Dated: New York, New York
January 12, 2006



DENISE COTE
United States District Judge